

PATENT COOPERATION TREATY

10/507442

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

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PCT

NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of Mailing
(day/month/year)

05 AUG 2005

Applicant's or agent's file reference

PRICE1300-1P

IMPORTANT NOTIFICATION

International application No.

International filing date (day/month/year)

Priority date (day/month/year)

PCT/US03/07968

13 March 2003 (13.03.2003)

13 March 2002 (13.03.2002)

Applicant

Q3DM, LLC

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.
4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/US

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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PRICE1300-1P	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US03/07968	International filing date (day/month/year) 13 March 2003 (13.03.2003)	Priority date (day/month/year) 13 March 2002 (13.03.2002)
International Patent Classification (IPC) or national classification and IPC IPC(7): G01N 33/48 and US Cl.: 702/19		
Applicant Q3DM, LLC		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 3 sheets, including this cover sheet.
- ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of ___ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of report with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 01 October 2003 (01.10.2003)	Date of completion of this report 21 July 2005 (21.07.2005)
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer Marjorie A. Moran Telephone No. (571) 272-1600 MARJORIE A. MORAN PRIMARY EXAMINER <i>Valerie Bell-Hopkins</i>

Form PCT/IPEA/409 (cover sheet)(July 1998)

I. Basis of the report**1. With regard to the elements of the international application:***

- ☒ the international application as originally filed.
- ☒ the description:
pages 1-51 as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.
- ☒ the claims:
pages 52 and 53, as originally filed
pages NONE, as amended (together with any statement) under Article 19
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.
- ☒ the drawings:
pages 1-31, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.
- ☐ the sequence listing part of the description:
pages NONE, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages NONE
- ☐ the claims, Nos. NONE
- ☐ the drawings, sheets/fig NONE

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

** Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

*** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. STATEMENT**

Novelty (N)	Claims <u>1-10</u>	YES
	Claims <u>NONE</u>	NO
Inventive Step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-10</u>	NO
Industrial Applicability (IA)	Claims <u>1-10</u>	YES
	Claims <u>NONE</u>	NO

2. CITATIONS AND EXPLANATIONS

Claims 1-10 meet the criteria set out in PCT Article 33(2), because the prior art does not teach the entirety of the instantly claimed invention in one reference.

Claims 1-10 lack an inventive step under PCT Article 33(3) as being obvious over RAAM (U.S. Patent Number 6,162,606); in view of LEE (U.S. Patent 5,528,703). RAAM describes the detection of tumor defects, exemplified via Estrogen receptors, wherein drug effects alter translocation behavior of cellular components as summarized in the abstract. Specific intracellular inter-compartment translocation between cytoplasmic and nuclear compartments is described in column 2, lines 3-9. An overall summary of the central details of the invention of RAAM is set forth in column 19, line 52, through column 21, line 12, which also set forth the effects of a drug agent on intracellular translocation. Various drug agents are listed generically in column 15, lines 26-34. Imaging of microscope slides containing cells and tissues containing cells for the analysis of RAAM is set forth in column 9, line 17, through column 11, line 4, including automation of the analysis. Another specific nuclear vs. cytoplasmic translocation in the reference is set forth in procedure D in columns 17-19 wherein specific translocation between intracellular compartments are analyzed as stated in column 18, lines 22-26. Thus, RAAM describes the basic drug agent induced translocation imaging of the instant invention but lacks a description of separating overlapping cell images as also instantly claimed.

LEE is an improvement invention on cellular imaging which describes details of size, shape, and location identification in the abstract including masking to assist in this process. LEE recognizes overlapping cell images in several citations including depicting this in Figures 11A and 11F. LEE motivates the improvement therein describes to improve cellular imaging processes in column 1, lines 45-67, via solving problems encountered in images due to proximate objects and prior art complex sample preparation to reduce such concerns. The specific problem of overlapping cells in images is described in LEE in column 5, lines 38-52, including the improvement of removing such overlaps thus separating cell images as instantly claimed. Column 6, lines 1-14, adds more detail to this separation procedure as well as specifics in column 9, line 35, through column 10, line 4. Column 10, lines 5-40, describes the masking practice which is the reasonably a tessellating method as present in certain instant claims for delineating cellular objects. Contrast enhancement of background vs. cellular object images as cited in certain instant claims such as claim 2, for example, is set forth in LEE in column 7, lines 30-37.

Thus, it would have been obvious to a practitioner in the art at the time of the instant invention to practice the basic drug agent induced translocation studies of RAAM along with the motivated improvement of cellular object imaging of LEE to result in the practice of the instant invention.

Claims 1-10 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry for cellular drug effect testing.

----- NEW CITATIONS -----

US 5,528,703 A (LEE) 18 June 1996, see entire document.